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10/562,183

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Yinhua Zhang

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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

NOTIFICATION DATE

DELIVERY MODE

12/10/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/562,183	<b>Applicant(s)</b> ZHANG ET AL.	
	<b>Examiner</b> GARY W. COUNTS	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the claims**

The amendment filed August 12, 2008 is acknowledged and has been entered. Currently, claims 1-11, and 14-22 are pending. Claims 18-22 are withdrawn as being directed to a non-elected invention. Claims 1-11 and 14-17 are under examination.

### **Withdrawn Rejections**

All rejections of claims not reiterated herein, have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is vague and indefinite because it is unclear if the CBD is fused to a carrier protein linked to a reporter or if the carrier protein is a fusion molecule linked to a reporter where the carrier protein is directed to a CBD. The claim does not make clear if the CBD is fused to a carrier protein or not.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al (Expression and Characterization of the Chitin-Binding domain of Chitinase A1 from *Bacillus circulans* WL-12, *Journal of Bacteriology*, June 2000, p. 3045-3054) in view Chong et al (*Gene* 192, (1997) 271-281 and further in view of Novokhatny (*Protein Science* (1997), 6:141-146).

Hashimoto et al discloses a method of detecting chitin in a sample. Hashimoto et al disclose contacting a reagent of chitin-binding domain with a sample containing chitin. Hashimoto et al disclose that the chitin-binding domain is CHBD<sub>ChiA1</sub> (p. 3047, p. 3048, p. 3051 & Figs. 1-3. Hashimoto et al disclose detecting the binding between the chitin-binding domain and the chitin. Hashimoto et al disclose that this chitin-binding domain bound only to chitin and that no significant binding to cellulose or other polysaccharides was detected (p. 3051, 2nd col). Hashimoto et al discloses that the

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binding domain was obtained from Chitinase a1 from *Bacillus circulans* (abstract, p. 3045).

With respect to claim 9 as indicated by applicant on page 10 of the specification, chitinase A1 contains CBD that belongs to CBM12. Thus, it is inherent that the CBD of Hosimoto et al has a carbohydrate-binding module corresponding to CBM12.

Hashimoto et al differs from the instant invention in failing to teach the chitin-binding domain is fused to a maltose-binding domain.

Chong et al teaches that it is known in the art to construct fusion proteins comprising CBD fused to maltose binding protein.

Novokhatny discloses that it is well known in the art to use maltose binding protein as a carrier protein for the production of recombinant fusion proteins in E-Coli. Novokhatny teaches that the presence of maltose binding protein facilitates purification of a target protein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce and incorporate a CBD-MBP fusion protein for the method of Hashimoto et al because Hashimoto et al specifically teaches that the CBD can be produced in E-Coli and Chong shows that it is well know in the art to fuse CBD-MBP and because Novokhatny teaches that the incorporation of a carrier protein such as maltose binding protein provides for purification of the target protein.

6. Claims 2, 3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al in view of Chong et al and Novokhatny et al as applied to claims 1, 9 and 11 above, and further in view of Gray et al (US 6,399,571).

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See above for the teachings of Hashimoto et al., Chong et al., and Novokhatny et al.

Hashimoto et al., Chong et al., and Novokhatny et al. differ from the instant invention in failing to specifically teach the chitin-binding domain comprises a reporter and also fail to teach an antibody to chitin-binding domain.

Gray et al teaches that it is known in the art to label chitin-binding domains with a reporter to detect chitin in a sample (col 7, lines 45-63). Gray et al also teaches the use of labeled antibodies that specifically bind to chitin-binding domains for detection of chitin-binding domain (col 6). Gray et al discloses that the reporter can be a radioisotope, fluorophore or enzyme (col 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a reporter such as taught by Gray et al into the modified method and chitin binding domain of Hashimoto, Chong, and Novokhatny because Hashimoto et al teaches that the chitin binding domain can be used in binding assays to determine chitin in a sample and Gray et al teaches that it is conventional in the art to label chitin-binding domains to provide for reagents to detect chitin in a sample. It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate chitin-binding domain antibodies as taught by Gray et al into the modified method of Hashimoto et al, Chong, and Novokhatny because Gray et al teaches that it is conventional in the art to utilize chitin antibodies in methods for detecting chitin in a sample.

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7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al in view of Chong et al and Novokhatny et al as applied to claims 1, 9 and 11 above, and further in view of Tuse et al (WO 92/17786).

See above for the teachings of Hashimoto et al., Chong et al., and Novokhatny et al.

Hashimoto et al., Chong et al., and Novokhatny et al. differ from the instant invention in failing to teach the sample is an animal or plant fluid.

Tuse et al disclose methods of detecting chitin in samples. Tuse et al disclose that the sample can be mammalian and plant fluid, tissues or water (p. 5 and p.9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a sample such as taught by Tuse et al into the modified method of Hashimoto et al, Chong, and Novokhatny because Tuse et al teaches applications of his samples for detection of the presence of chitin.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al in view of Chong et al and Novokhatny et al as applied to claims 1, 9 and 11 above, and further in view of Harman et al (US 6,251,390).

See above for the teachings of Hashimoto et al., Chong et al., and Novokhatny et al.

Hashimoto et al., Chong et al., and Novokhatny et al. differ from the instant invention in failing to teach bleaching the sample.

Harman et al disclose that it is known in the art to bleach a sample of chitin which provides for purification of the chitin (col 3, lines 34-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to bleach the sample of Hashimoto et al because Haman et al teaches that it is known in the art to bleach samples of chitin in order to provide for purification of the chitin.

9. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al., in view of Chong et al., Novokhatny et al and Gray et al as applied to claims 1-3, 6-9 and 11 above, and further in view of Tuse et al and Foster et al.

See above for the teachings of Hashimoto et al., Chong et al., Novokhatny et al and Gray et al.

Hashimoto et al., Chong et al., Novokhatny et al and Gray et al., differ from the instant invention in failing to teach the components packaged into a kit and also fails to teach instructions and an immobilized CBD reagent.

Tuse et al teaches methods and kits for detecting chitin. Tuse et al disclose chitinase reagents which specifically bind to chitin (p. 4). Tuse et al disclose that a chitin binding domain can be immobilized to a solid support and used to capture chitin and subsequently detected to determine the chitin. Tuse et al teach that these methods provide for the advantage of detecting chitin in samples of all types of biological fluids and tissues and also provide the advantage of an efficient, economical, clinical laboratory assay for the rapid diagnosis of fungal inflections in patients.



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Foster et al disclose instructions (packaging material) packaged in a kit for using the kit (col 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate immobilized chitin binding domain such as taught by Tuse et al into the modified method of Hashimoto et al because Hashimoto specifically teaches that binding assays can be used to determine the chitin in a sample and Tuse et al shows that immobilized chitin binding domain reagents provide for detecting chitin in samples of all types of biological fluids and tissues and also provide the advantage of an efficient, economical, clinical laboratory assay for the rapid diagnosis of fungal infections in patients. It would have also been obvious to one of ordinary skill in the art at the time the invention was made to package the components into a kit as taught by Foster because Tuse et al teaches that it is known in the art to package components into a kit and further one of ordinary skill in the art would recognize that this would make it more convenient and facile for the test operator.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate instructions as taught by Foster et al. into the modified method and kit of Hashimoto et al because Foster et al shows that instructions provide for the use of kits and one skilled in the art would recognize that the addition of instructions would make it more convenient and facile for the test operator.

### ***Response to Arguments***

10. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1641

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